

October 24, 2005

Massachusetts Emergency Contraception Network

c/o NARAL Pro-Choice Massachusetts

41 Winter Street, Suite 65

Boston, MA 02108

Acting Commissioner Andrew C. von Eschenbach

Food and Drug Administration

Division of Dockets Management

5630 Fishers Lane, Rm. 1061

Rockville, MD 20852

Re: Docket No. 2005N-0345 / RIN 0910-AF72

Dear Acting Commissioner von Eschenbach,

We, a coalition of health care providers, pharmacists, advocates, research organizations and public health officials, are writing in regards to the FDA's recent announcement to yet again postpone the decision on over-the-counter status for the emergency contraceptive pill marketed as Plan B. The FDA's purposeful indecision is denying women timely access to a safe, effective chance to prevent pregnancy after sex. Unable to justify saying "no" to over-the-counter Plan B in the face of overwhelming evidence, the agency issued a "back-door" denial by deferring its decision indefinitely. The longer the agency drags this process out, the more women have to play "beat the clock" after their birth control fails or they had sex when they didn't expect or want to.

By shifting the focus to regulatory issues, the FDA has turned drug approval into a political process and has created a new roadblock to improving women's access to back-up birth control. It is unacceptable that what should be a scientific inquiry has ended up as a question of politics. This clear example of the FDA allowing politics to trump science is intolerable.

The FDA has failed in its duty to heed science and promote public health. An unprecedented medical and scientific consensus – inside and outside the FDA – agrees that women of all ages can use emergency contraception safely and effectively without a prescription. Despite the recommendation of the FDA's own advisory committees, the agency has refused to approve over-the-counter Plan B, sidestepping its obligation to act on the scientific evidence and promote public health.

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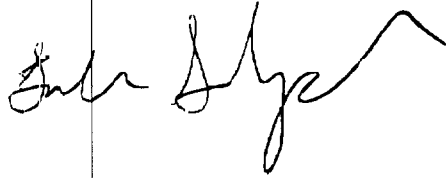
As the new Acting Commissioner, you have the opportunity to set the FDA back on the right track. Science tells us that Plan B should be made available to women of all ages without a prescription. Turning this process over to rulemaking is an unnecessary delay tactic with thinly veiled political motives. It is time for the FDA to stop playing politics with women's lives and to restore public confidence in the agency. We urge the FDA to abandon the rulemaking process and to approve the Plan B over-the-counter application so that women of all ages can have access to EC without delay.

Sincerely,

Sarah Schupbach

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10-24-05

Stacie Garnett

Massachusetts Emergency Contraception Network Coordinator

Steering Committee Members:

Boston Public Health Commission

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Jane Doe, Inc.

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Northeastern University School of Pharmacy

Planned Parenthood League of Massachusetts

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